

Prevention of breast edema with a compression bra (CoBra)

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23066

Source

Nationaal Trial Register

Brief title

CoBra

Health condition

Breast cancer
Radiotherapy
plastic surgery

Borstkanker
Radiotherapie
Plastische Heelkunde

Sponsors and support

Primary sponsor: University of Antwerp
in corporation with the Antwerp University Hospital

Source(s) of monetary or material Support: Initiator = Sponsor
in corporation with:
Juzo Gmbh
Tiicolast NV

Intervention

Outcome measures

Primary outcome

Incidence of breast edema

Secondary outcome

-Comfort compression bra

-Pressure (Picopress)

-Compression questionnaire

-Water content of dermis and subcutis

-QoL (McGill QoL Dutch)

Study description

Study objective

Wearing a compression bra, early after surgery, will be preventive for the development of breast edema.

Study design

T0 = baseline

T1 = 1mo FU

T2 = 3mo FU

T3 = 6mo FU

Intervention

Wearing a custom-made compression bra early after surgery

Contacts

Public

University of Antwerp
Universiteitsplein 1

Nick Gebruers
Wilrijk 2610
Belgium

Scientific

University of Antwerp
Universiteitsplein 1

Nick Gebruers
Wilrijk 2610
Belgium

Eligibility criteria

Inclusion criteria

- Female patients with breast cancer who will receive breast conserving surgery.
- Female patients that are candidates for plastic surgery (breast reduction or breast enlargement)
- Age > 18y
- Able to understand Dutch
- providing a signed informed consent

Exclusion criteria

- metastatic breast cancer
- DIEP-flap reconstructive surgery

-open wounds

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-05-2016
Enrollment:	76
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5619
NTR-old	NTR5726
Other	: V2016_3_10

Study results

Summary results

Verbelen H, Gebruers N, Beyers T, De Monie AC, Tjalma W. Breast edema in breast cancer patients following breast-conserving surgery and radiotherapy: a systematic review. Breast Cancer Res Treat. 2014 Oct;147(3):463-71. doi: 10.1007/s10549-014-3110-8. Epub 2014 Aug 28. PubMed PMID: 25164973.